K003342

JAN 2 2 2001

Wako

Wako Chemicals USA, Inc.

1600 Bellwood Road, Richmond, VA 23237 U.S.A.

Telephone (804) 271-7677 Telex 293208 WAKO UR(RCA) Facsimile (804) 271-7791

510(K) Summary of Safety and Effectiveness

Intended use

The Wako CRP-UL test is an in vitro assay for the quantitative determination of C-reactive protein (CRP) in serum. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Summary and explanation of the test

A protein that binds the C-polysaccharide on the cell wall of *Streptococcus pneumoniae* presents in the sera of acutely ill patients. This protein is called C-reactive protein (CRP), which has been recognized as one of the acute phase reactants that rise dramatically in the case of inflammation or tissue destruction. Determination of CRP is clinically useful for detecting inflammation and infections. Additionally, measurement of CRP by high sensitivity assays may add to the predictive value of other markers used to assess the risk of cardiovascular and peripheral vascular disease.[4-10] When using CRP to assess risk of cardiovascular and peripheral vascular disease, measurement should be compared to previous values. Various methods can be used for the determination of CRP (e.g. turbidimetric immunoassay (TIA), nephelometric immunoassay (NIA) and latex immunoassay (LIA)). The CRP-UL test is highly specific reagent based on latex immunoassay.[1,2]

Principle:

When a sample is mixed with Buffer and Latex Reagent, CRP in the sample combines specifically with the latex sensitized with anti-human CRP antibody (goat) in the Latex Reagent to yield an insoluble aggregate that causes increased turbidity in the solution. The degree of turbidity of solution can be measured optically and is proportional to the concentration of CRP in the patient's sample.

Precision studies indicate acceptable values can be obtained on a day to day basis. The minimum detectable level of this method is estimated to be 10 ug/dL in the case of 3 ul sample volume, and 5 ug/dL in the case of 5 ul sample volume.

References

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2. Wolfgang Koening. et al.: Circulation. 99,237-242 (1999)
3. DG Klinische Chemie Mitteilungen 26 (1995) page5.
4. Ridker PM, Cushman M, Stampler MJ, Tracy RP, Hennekens CH, Plasma concentration of C-Reactive Protein and risk of developing peripheral vascular disease. Circulation. 1998: 97: 425-428.

5. Ridker PM, Buting JE, Shih J, Matlas M, Hennekens CH. Prospective study of C-reactive protein and the risk of future cardiovascular events among apparently healthy women. Circulation 1998: 98;731-733.
6. Ridker PM, Glynn RJ, Hennekens CH. C-reactive protein adds to the predictive value of total and HDL cholesterol in determining risk of first myocardial infarction. Circulation 1998: 97; 2007-2011.
7. Ridker PM, Rifai N, Pefler MA, Sacks FM, Moye LA, Golman S, Flaker GC, Braunwald E, for the Cholesterol and recurrent events (CARE) Investigators. Inflammation, Prevastatin, and the risk of coronary events after myocardial infarction in patients with average cholesterol levels. Circulation 1998: 98;839-844.
8. Tracy RP, Lemaltro RN, Peaty BM, Ives DG, Evans RW, Cushman M, Mellahn EN, Kuller LH. Relationship of C-reactive protein to risk of cardiovascular disease in the ederly; results from the Cardiovascular Health Study and the Rural Health Promotion Project. Arterioscler Thrombo Vaso Biol, 1997; 17:1121-1127.
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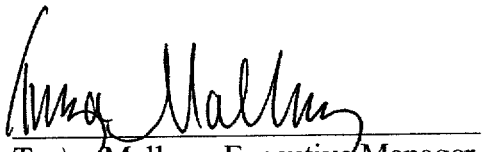
10. Ridker PM, Cushman M, Stampfor MJ, Tracy RP, Hennakens CH. Inflammation, aspirin and the risk of cardiovascular disease in apparently healthy men. N Engl J Med 1997; 336:973-979.

Signed: 

Tonya Mallory, Executive Manager
October 5, 2000
Wako Diagnostics
1600 Bellwood Road
Richmond, VA 23237
Telephone: 804-714-1925

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 2 2001

Ms. Tonya Mallory
Executive Manager
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, Virginia 23237

Re: K003342
Trade Name: Wako CRP-UL Assay
Wako CRP-UL Calibrator Set
Regulatory Class: II
Product Code: DCN, JIS
Dated: December 27, 2000
Received: December 28, 2000

Dear Ms. Mallory:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003342

Device Name: Wako CRP-UL

CRP-UL Calibrator Set

Indications For Use:

Wako CRP-UL:

The Wako CRP-UL assay is an invitro diagnostic test for the quantitative determination of c-reactive protein in human serum ~~as~~ by means of latex immunoassay. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases.

Wako CRP-UL Calibrator Set:

The Wako CRP-UL Calibrator set is designed to be used with Wako CRP-UL test for the determination of C-reactive protein in serum.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K003342

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)